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10/045,550	10/26/2001	Eldon H. Nyhart JR.	BIO-P0001.02	3390
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BAKER & DANIELS LLP 300 NORTH MERIDIAN STREET SUITE 2700 INDIANAPOLIS, IN 46204			EXAMINER THANH, LOAN H	
			ART UNIT 3763	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Application Number: 10/045,550  
Filing Date: October 26, 2001  
Appellant(s): NYHART, ELDON H.

**MAILED**  
**OCT 09 2007**  
**Group 3700**

\_\_\_\_\_  
Ryan C. Barker  
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/13/07 appealing from the Office action  
mailed 11/03/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6086582	Altman et al.	07-2000
6028068	Chupakhin et al.	02-2000
4789673	Donatsch et al.	09-1994
4146029	Ellinwood, Jr.	03-1979

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57-59,62,64,105-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman et al. ( US 6,086,582).

Altman et al. disclose a method of providing a compound to a system comprising a catheter having a drug which is releasably captured in the matrix, a source of electrical energy 1052 which is activated to release the drug from the matrix 1060, a controller which senses electrical activity of the heart and responds by injecting delivery of the drug or goes into monitoring mode depending on the sensed electrical activity. See column 14, lines 7-47 and col. 14, line 66 to col. 15, lines 47. With respect to claims 64, Altman et al. disclose the releasing of the drug depends on the sensed electrical activity and as such, it is considered to releasing predetermine amounts of compounds at variable intervals. See column 16, lines 2-8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. ( US 6,086,582) in view of Chupakhin et al. ( US 6,028,068).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. does not disclose the therapeutic agent is anesthetic and the system to be the neurological system. Chupakhin et al. teach 6H-

1,3,4-thiadiazin-2-amines drugs used in medicine acting as anesthetics, cardiovascular and hypometabolic agents. Specifically, Chupakhin et al. teach that anesthetic agents act as respiratory and cardiovascular depressants. Further, agents have been identified as having anesthetic and cardiovascular property, which are used in brain and myocardial infarction. Anesthetics are a drug class which is well known for acting on the neurological system. It would have been obvious to one of ordinary skill in the anesthesia art to substitute the cardiovascular drug of Altman et al. with the 6H-1,3,4-thiadiazin-2-amines which could treat the patient in a life-threatening situation with the properties of the being an anesthetic and cardiovascular agent which act on the circulatory and neurological system.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. ( US 6,086,582) in view of Donatsch et al. ( US 4,789,673).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. However, Altman et al. is silent to a neurotransmitter as an agent in the neurological system of the biological unit. Donatsch et al. teach serotonin M receptor antagonists for the treatment of pain, migraine, vascular and treatment of heart circulation disorders. Serotonin receptors are located in the nervous system of the GI track, the heart, the bladder and the adrenal glands. It would have been obvious to one of ordinary skill in the medical art to substitute the cardiovascular drug of Altman et al. with another cardiovascular drug such as the Serotonin M receptor antagonist of Donatsch et al. in order to treat heart circulation disorders.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. ( US 6,086,582).

Altman et al. disclose the invention as substantially claimed. See above. However, Altman et al. is silent to the control signal having a frequency content of less than about 1 Hz. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frequency to about 1 HZ since it lacks criticality and this parameter is deemed matters of choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 65 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. ( US 6,086,582) in view of Ellinwood, Jr. ( US 4,146,029).

Altman et al. discloses the invention as substantially claimed. See above. Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents. Altman et al. teach a controller for releasing an amount of drug at variable intervals. However, Altman et al. is silent to releasing variable amounts of the compound at predetermined intervals or releasing variable amounts of the drug at variable intervals. Ellinwood, Jr. teaches a programmable controller for a medication system. See figures 1-11. Ellinwood, Jr. teaches 1/sensing, timed evaluation, with decision control, 2/periodic sensing and screening control, 3/periodic sensing, data evaluation with dosage control, 4/periodic sensing, data evaluation and alternate dosage selection, and 5/sensing, controlled same dosage with different amounts for different conditions. See column 3, lines 9-46, and column 4, lines 39-42. Ellinwood,

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Jr. further discloses that a large number of variables can be programmed to match both the immediate and changing conditions of a wide range of patient needs. Thus, it would have been obvious to modify the predetermined amount of the drug and/or the interval time of Altman et al. with variable amounts of drug and/or variable interval times as taught by Ellinwood, Jr. in order to provide a more effective treatment method for the varying need of the patient condition.

#### **(10) Response to Argument**

Applicant's arguments filed 08/24/06 have been fully considered but they are not persuasive. Applicant's argument that Altman et al. is silent or does not teach the limitation of "preparing a control signal using fractal mathematics" is not convincing. The Examiner is taking the position that the control signal is prepared by using fractal mathematics. It is being considered that the computer/controller is inherently producing fractal mathematics since fractals are generated by an iterative process - doing the same thing again and again. The computer/controller has this factor built in. Fractals also have the property that when you magnify them they still look much the same. The device of Altman produces the same control signal to release the compound. Further, if fractal mathematics is considered to be calculations based on fractions, any integer is considered to be a fraction or could be represented as a fraction.



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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


LoAn H. Thanh



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